AMENDMENTS TO THE SPECIFICATION

Page 1, after the title insert the following:

This application is the US national phase of international application **PCT/EP2004/008486**, filed **29 July 2004**, which designated the U.S. and claims priority of **IT MO2003A000230**, filed **7 August 2003**, the entire contents of each of which are hereby incorporated by reference.

Please amend the paragraph beginning at page 4 line 24, as follows:

A yet further object is to provide a device ~~per~~ for transcutaneous biopsy in which it is possible to remove the sample at the root without performing complex procedures.

Please amend the paragraph beginning at page 5 line 1, as follows:

~~In a first aspect of~~According to the invention, a device is provided for taking a sample of biological tissue transcutaneously, comprising: a needle ~~means~~ arrangement having a tubular-shaped body, having an end associable with a grip and being provided with an edge free at the opposite end, lamina ~~means~~ elements movable between a neutral position wherein ~~it~~ they lies near said tubular-shaped body and an operating position wherein ~~it~~ they are~~is~~ distanced from the latter, ~~characterized in that~~wherein said lamina elements~~means~~ protrude~~s~~ towards said end.

Please amend the paragraph beginning at page 5 line 11, as follows:

Owing to ~~this aspect of~~ the invention, it is possible to create a biopsy device in rather a simple manner because the lamina elements ~~means~~ can be an integral part of the needle arrangement~~means~~.

Please amend the paragraph beginning at page 5 line 15, as follows:

Furthermore, to actuate the lamina elements~~means~~ it is sufficient to extract the device from the body of the patient subjected to biopsy. In fact, since the lamina elements~~means~~ point~~s~~ towards the grip of the device, it tends during extraction of the latter to engage automatically in the sample, cutting a root portion thereof.

Please delete the paragraph beginning at page 5 line 21, as follows:

~~In a second aspect of the invention, a device is provided for taking a sample from a biological tissue transcutaneously, comprising: needle means having a tubular-shaped body, provided with an end associable with a grip and with an edge free at the opposite end, characterized in that said needle means comprises window means shaped in such a way that said sample can be extracted by said device through said window means.~~

Please delete the paragraph beginning at page 5 line 29, as follows:

~~Owing to this aspect of the invention, to extract the sample from the device it is sufficient to remove the sample through the above window means without having to use the probe.~~

Please amend the paragraph beginning at page 6 line 30, as follows:

With reference to figures 1 to 3, a device 1 for conducting bone-marrow biopsies comprises a hollow needle 2 having an outer tubular body (2a) and ~~with a cylindrical tubular shape, having~~ a proximal end provided with a known operating grip, which is therefore neither shown or disclosed in detail, and a tapered distal end 5 that is provided with a cutting edge 6.

Please amend the paragraph beginning at page 7 line 3, as follows:

A tubular ~~element~~body 3, inside which a stem 4 is slidingly insertable is slidingly insertable inside the hollow needle 2 and is arranged to arrest inside itself a sample 25 taken from the patient according to a manner that will be disclosed in greater detail below. The tubular body~~element~~ 3 comprises a cylindrical wall 8 delimiting a tubular cavity 10 interposed between a further proximal end that is not shown, provided with an operating grip of the known type, which is not shown, and further distal end 7 provided with a circular edge 12. The cylindrical wall 8, near the further distal end 7, is provided with a release window 13, arranged to allow the extraction of the sample 25 at the end of the biopsy. The release window 13 is delimited by a pair of straight

borders 14, an arched proximal border 15 and an arched distal border 16. The straight borders 14 are parallel to one another and to a longitudinal axis of the tubular ~~element~~body 3 and are connected with the arched proximal border 15 and with the arched distal border 16. The arched proximal border 15 is tilted towards the further proximal end of the tubular ~~element~~body 3, such as to delimit with the straight borders 14 a pair of equal obtuse angles, which are not shown. The arched distal border 16 is tilted in the direction of the further distal end 7, such as to form with the straight borders 14 a pair of equal obtuse angles that are not shown, the obtuse angles having the same degree as the degree of the obtuse angles formed by the arched proximal border 15 with the straight borders 14. A further embodiment of the tubular ~~element~~body 3 is also provided that is not shown that is made without the release window 13. In the cylindrical wall 8, between the release window 13 and the further distal end 7, three V-shaped notches 9 are obtained with the apex pointing towards the further proximal end of the tubular ~~element~~body 3.

Please amend the paragraph beginning at page 8 line 3, as follows:

At each notch 9 a triangular lamina, or appendage, 11 is defined by a portion of cylindrical wall 8 that is near the notch 9 and points to the further proximal end of the tubular ~~element~~body 3. Each lamina 11 has a free cutting border 23 and a constrained border 24, indicated by a broken line, which is straight and integral with the remaining cylindrical wall 8. Each lamina 11 is furthermore slightly bent towards a longitudinal

axis of the tubular ~~element~~body 3, in such a way as to protrude, if there is no opposing movement, inside the tubular cavity 10, as indicated by the broken lines in Figure 3.

Please amend the paragraph beginning at page 8 line 14, as follows:

The prior-art stem 4 comprises a cylindrical rod 17 made with a transverse section such as to enable it to slide inside the tubular cavity 10. The rod is interposed between a yet further proximal end that is not shown provided with an operating grip that is not shown and a yet further distal end 18 comprising a penetration point 19. The length of the stem 4 is greater than the length of the tubular ~~element~~body 3 and of the hollow needle 2, so that the penetration point 19 protrudes outside the distal end 5 when the device 1 is assembled.

Please amend the paragraph beginning at page 8 line 23, as follows:

Figure 11 shows a yet further embodiment of the device 1 that does not comprise the tubular ~~element~~body 3, since the laminae 11 are obtained directly in the wall of the hollow needle 2.

Please amend the paragraph beginning at page 8 line 26, as follows:

With reference to Figures 4, 5 and 6, when the device 1 is assembled for use, inside the hollow needle 2 the tubular ~~element~~body 3 is positioned and inside the latter the

stem 4 is located, with the penetration point 19 protruding from the distal end 5. During this phase, the rod 17 compresses the laminae 11, preventing the latter from protruding inside the tubular cavity 10. To perform a bone-marrow biopsy on a patient, an operator, after positioning the device 1 assembled near the anatomical region housing a preselected bone formation, for example the iliac crest, makes the hollow needle 2 penetrate the underlying tissues in a penetration direction F1. As shown in Figure 4, where for the sake of simplicity the layers of skin and muscular tissue have been omitted, when the hollow needle 2 gets near a bone 20, the penetration point 19 is used by the operator to perforate a surface layer of particularly resistant compact bone tissue 21. The stem 4 is then removed and the hollow needle 2 containing the tubular ~~element~~body 3 is pushed deeper into the bone 20 so as to reach an underlying spongy bone tissue 22. The latter tends to penetrate inside the tubular cavity 10 as the hollow needle 2 continues to progress into the bone 20, thereby causing the formation of the approximately cylindrical sample 25, which remains connected to the surrounding spongy bone tissue 22 only near its distal end or root 26.

Please amend the paragraph beginning at page 9 line 26, as follows:

When the desired sample depth has been reached, the operator can proceed to extract the device 1 by acting in direction F2 opposite the penetration direction F1. To remove the sample 25 from the surrounding tissue 22, it is not necessary to perform any dislocating movement. In fact, by simply extracting the hollow needle 2 and the coaxial tubular ~~element~~body 3 in the direction F2, the laminae 11, thanks to their initial

tilt, progressively engage with the sample 25. The latter presses on the laminae 11, which bend and approach one another near the longitudinal axis of the tubular ~~element~~body 3, tending to close the tubular cavity 10. It is therefore sufficient for the operator to rotate only slightly the device 1 around the longitudinal axis of the latter for the free cutting borders 23 of the laminae 11 to separate the root 26 of the sample 25 from the surrounding spongy bone tissue 22. The laminae 11, in their folded position, hold the sample 25 in the tubular cavity 10.

Please amend the paragraph beginning at page 10 line 9, as follows:

Once the sample 25 has been held in the tubular cavity 10, the operator can first remove the device 1 from the body of the patient and then the tubular ~~element~~body 3 from the proximal end of the hollow needle 2 in such a way as to recover the sample 25 via the release window 13. In this way, the sample is extracted from the device 1 without recourse to further instrumental procedures, i.e. the operator is not obliged to slide a probe inside the tubular ~~element~~body 3 until the ejection of the sample 25 is obtained.

Please amend the paragraph beginning at page 10 line 27, as follows:

With reference to Figures 7 and 8, an inner ~~further~~ tubular ~~element~~body 27, fashioned in the shape of a hollow cylinder that is slidingly insertable inside the tubular ~~element~~body 3, is positioned in the latter in such a way that one of its distal closing

ends 28 is at a certain distance from the laminae 11. The tubular ~~element~~body 3, which in this embodiment is provided with a distal end, which is not shown and has for example the shape of an oblique cut, can in turn be inserted into the hollow needle 2 (not shown for the sake of simplicity in Figures 7 to 10). The device 1 is made to penetrate into the body of a patient by an operator until it reaches a desired depth, in such a way as to cause the formation of a sample of soft tissue, not shown, which remains contained inside the apparatus 1. At this point, the operator slides the ~~further~~ inner tubular ~~element~~body 27 inside the tubular ~~element~~body 3 in direction F1 indicated by the arrow so that the closing end 28 engages with the laminae 11 bending them towards a longitudinal axis of the device 1. The laminae 11, by flexing, resect the root of the sample, which is not shown, isolating the latter from the surrounding tissue, which is not shown. The sample thus remains enclosed inside the device 1, and can thus be easily extracted together with the latter from the body of the patient.

Please amend the paragraph beginning at page 11 line 14, as follows:

In another embodiment shown in Figures 9 and 10, as an alternative to the ~~further~~ inner tubular ~~element~~body 27, an outer ~~yet further~~ tubular body 29 is provided that is shaped in such a way as to be slidingly interposable between the hollow needle 2 and the tubular ~~element~~body 3. The ~~yet further~~outer tubular body 29 distally comprises three protuberances 30 reciprocally angularly spaced by approximately 120° and having their convexity turned towards the cylindrical wall 8 of the tubular ~~element~~body 3. Owing to a longitudinal incision 31 obtained in the wall of the ~~yet further~~outer tubular

body 29, the latter can be forced against the cylindrical wall 8. In this way, by positioning the ~~yet further~~outer tubular ~~element~~body ~~30~~ 29 at a certain distance from the notches 9, each protuberance 30 is applied outside the cylindrical wall 8. In use, after a sample of tissue, which is not shown, has been enclosed inside the device 1, the operator slides ~~the yet further~~outer tubular body 29 in the direction F1 indicated by the arrow. In this way the protuberances 30 engage with the laminae 11, flexing them and the free cutting borders 23 of the latter resect the root that is not shown of the tissue sample. The latter, separated by the surrounding tissue, remains enclosed within the device 1 and can be removed together with the latter from the body of the patient.